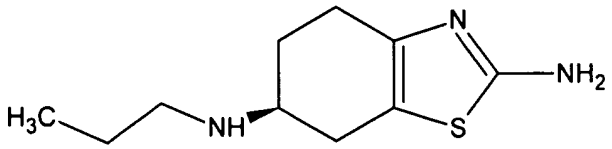
CLAIMS

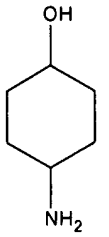
1. (original) An improved process for the preparation of (S)- 2,6-diamino-4,5,6,7-tetrahydro benzothiazole of formula II an intermediate compound for formation of Pramipexole of Formula (I) and its pharmaceutically acceptable salts, solvates



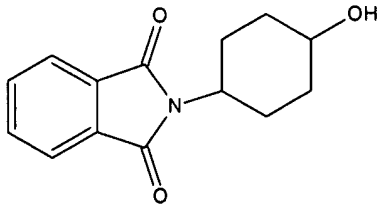
(I)

comprising the steps of

(a) reacting 4-amino cyclohexanol of formula (III) or its acid addition salts with phthalic anhydride in presence of acid catalyst and their salts, in polar aprotic solvent or its mixture with organic solvent, capable of removing water azeotropically to give 4-(phthalimido)-cyclohexanol of formula (IV)

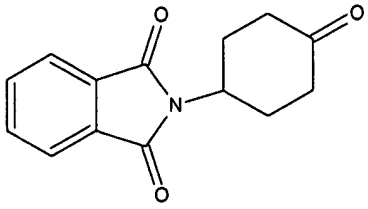


(III)



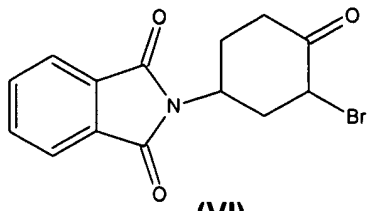
(IV)

(b) oxidizing 4-(phthalimido)-cyclohexanol of formula (IV) to give 4-(phthalimido)-cyclohexanone of formula (V)



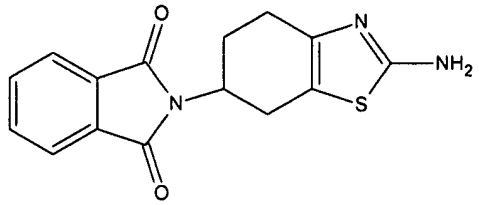
(V)

(c) brominating 4-(phthalimido)-cyclohexanone of formula (V) with brominating agent in organic solvent in presence of Lewis acid catalyst to prepare 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI)



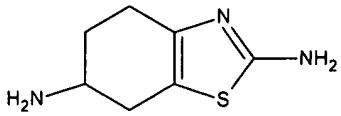
(VI)

(d) treating 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI) with thiourea in organic solvent in presence of base to give 2-amino-6-phthalimido-4,5,6,7-tetrahydro benzothiazol of formula (VII)



(VII)

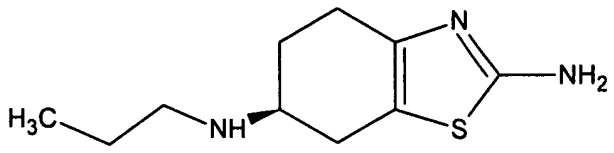
(e) reacting compound of formula (VII) with hydrazine hydrate and base in polar solvent to give racemic 2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (VIII)



(VIII)

(f) resolving racemic 2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (VIII) to prepare (6S)-2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (II)

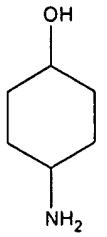
2. (original) An improved process for the preparation of Pramipexole of Formula (I) and its pharmaceutically acceptable salts/solvates



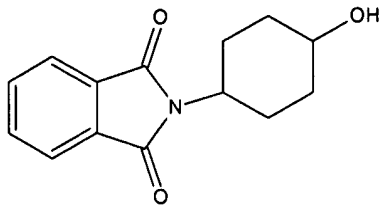
(I)

comprising the steps of

(a) reacting 4-amino cyclohexanol of formula (III) or its acid addition salts with phthalic anhydride in presence of acid catalyst and their salts, in polar aprotic solvent or its mixture with organic solvent, capable of removing water azeotropically to give 4-(phthalimido)-cyclohexanol of formula (IV)

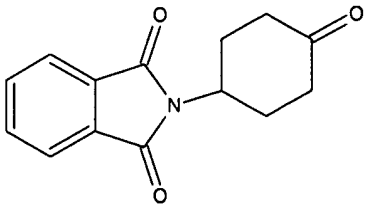


(III)



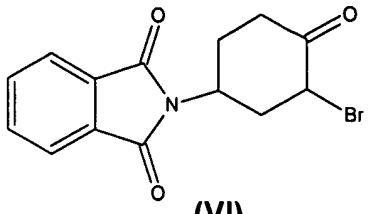
(IV)

(b) oxidizing 4-(phthalimido)-cyclohexanol of formula (IV) to give 4-(phthalimido)-cyclohexanone of formula (V)



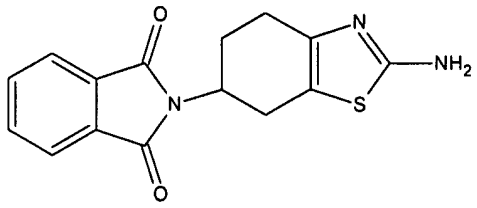
(V)

(c) brominating 4-(phthalimido)-cyclohexanone of formula (V) with brominating agent in organic solvent in presence of Lewis acid catalyst to prepare 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI)



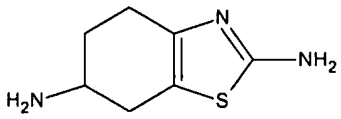
(VI)

(d) treating 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI) with thiourea in organic solvent in presence of base to give 2-amino-6-phthalimido-4,5,6,7-tetrahydro benzothiazol of formula (VII)



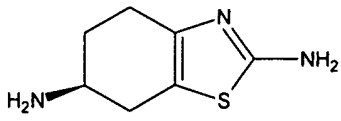
(VII)

(e) reacting compound of formula (VII) with hydrazine hydrate and base in polar solvent to give racemic 2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (VIII)



(VIII)

(f) resolving racemic 2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (VIII) to prepare (6S)-2,6-diamino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (II)



(II)

(g) coupling (6S)-2,6-dimino-4,5,6,7-tetrahydro-1,3-benzothiazole of formula (II) with propionaldehyde in presence of mineral acid in polar organic solvent and reducing agent to prepare (S)-(-)-2-Amino-6-(n-propylamino)-4,5,6,7-tetrahydrobenzothiazole of formula (I) ;and if desired

(h) converting (S)-(-)-2-Amino-6-(propylamino)-4,5,6,7-tetrahydrobenzothiazole to its pharmaceutically acceptable salts or solvates.

3. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein acid catalyst in step (a) is sulphonic acid and its salts with organic bases or salt of inorganic acids with organic bases.

4. (currently amended) A process as claimed in claim 1 ~~or 2~~ , wherein said acid catalyst is selected form the group comprising of p-toluene sulfonic acid, methane sulfonic acid, pyridine hydrochloride, pyridine hydrobromide, pyridine methane sulfonate, pyridine p-toluene sulphonate, picoline hydrochloride, picoline hydrobromide, picoline methane sulfonate, picoline p-toluene sulphonate, lutidine hydro chloride, lutidine hydrobromide, lutidine methane sulfonate, lutidine p-toluene sulphonate.

5. (original) A process as claimed in claim 4, wherein said acid catalyst is preferably pyridine p-toluene sulphonate, p-toluene sulfonic acid.

6. (currently amended) A process as claimed in claim 1~~or 2~~, wherein said polar aprotic solvent in step (a) is selected from group comprising of amide functional group such as dimethylformamide (DMF), dimethylacetamide (DMAC), N-methylpyrrolidinone (NMP), N-methylacetamide, N-methylformamide, , N,N-dimethylpropionamide, sulphoxide functional group such as dimethylsulfoxide, sulfolane, and ethers such as tetrahydrofuran (THF) and dioxane.

7. (original) A process as claimed in claim 6, wherein preferred solvent is Dimethyl formamide.

8. (currently amended) A process as claimed in claim 1~~or 2~~, wherein step (a) is carried out in mixture of polar aprotic solvent with organic solvent, capable of removing water azeotropically such as toluene, cyclohexane and the like

9. (currently amended) A process as claimed in 1~~or 2~~, wherein said step (a) is carried out at 90°C to 140° C.

10. (currently amended) A process as claimed in claim 1~~or 2~~, wherein said step (a) is carried out for 10 to 20 hrs and more preferably for 12 to 18 hrs.

11. (currently amended) A process as claimed in claim 1~~or 2~~, wherein brominating agent in said step (c) is bromine.

12. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein Lewis acid used as catalyst in said step (c) is selected form aluminum chloride zinc chloride and stannous chloride.

13. (original) A process as claimed in claim 12, wherein Lewis acid catalyst is preferably aluminum chloride

14. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein organic solvent in said step (c) is selected from halogenated, nonhalogenated organic solvents.

15. (original) A process as claimed in claim 14, wherein said halogenated solvent is methylene dichloride.

16. (original) A process as claimed in claim 14, wherein said nonhalogenated solvents is selected from alkyl acetate such as ethyl acetate, methyl acetate, propyl acetate and alcohols such as methanol, ethanol, and propanol.

17. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein base used in step (d) is selected from alkaline earth metal carbonate, bicarbonate, acetate.

18. (original) A process as claimed in claim 17, wherein base is selected from sodium carbonate, potassium carbonate, sodium bicarbonate, potassium bicarbonate, sodium acetate, potassium acetate, preferably sodium bicarbonate, potassium bicarbonate.

19. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein organic solvent used in step (d) is selected from alcohols, halogenated solvents or mixtures thereof.

20. (original) A process as claimed in claim19, wherein organic solvent used in step (d) is selected from methanol, ethanol, isopropranol, n-propanol, n-butanol, methylene dichloride, ethylenedichloride, chloroform, or mixtures thereof.

21. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein said step (d) can be carried out without isolating 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI) prepared in said step (c).

22. (currently amended) A process as claimed in 1 ~~or 2~~, wherein said step (d) is carried out *in situ* with thiourea.

23. (currently amended) A process as claimed in claim 1 ~~or 2~~, wherein organic base used in said step (e) is triethyl amine, pyridine, dimethy aniline, lutidines, picolines and DBU, preferably triethyl amine.

24. (original) A process as claimed in claim1 wherein said polar solvent in step (e) is selected from methanol, ethanol, isopropanol, n-propanol, n-butanol, iso-butanol or mixtures thereof.

25. (original) A process as claimed in claim 24, wherein preferred solvent is ethanol or isopropanol.

26. (currently amended) A process as claimed in claim1 ~~or 2~~, wherein said step (f) comprises the steps of

(i) treating *in situ* or racemic 2,6-diamino-4,5,6,7-tetrahydro benzothiazole of formula (VIII), obtained in step (d) with (L) –tartric acid to give (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole.

(ii) isolating pure (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole

(iii) converting pure (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole to (S)-2,6-diamino-4,5,6,7-tetrahydro benzothiazole of formula (II).

27. (original) A process as claimed in claim2, where in mineral acid used in said step (g) is selected from HCl, H_2SO_4, preferably H_2SO_4

28. (original) A process as claimed in claim 2, wherein reducing agent used in said step (g) is metal borohydride preferably sodium borohydride, sodium cyanoborohydride.

29. (original) A process as claimed in claim2, wherein polar organic solvent used in step (g) is selected from alcohols preferably methanol, ethanol, isppropanol, n-propanol or mixtures thereof.

30. (original) A process as claimed in claim 2, wherein the conversion of Pramipexole of Formula (I) to its pharmaceutically acceptable salts, solvates is carried out with respective acids in organic solvent selected from methanol, ethanol, ethyl acetate, isopropyl acetate.

31. (original) A process for the preparation of (S)- 2,6-diamino-4,5,6,7-tetrahydro benzothiazole an intermediate compound of formula II for formation of Pramipexole of Formula (I) such as herein described with particular reference to the examples.

32. (original) A process for the preparation of pramipexole of formula (I) and its pharmaceutically acceptable salts solvates as herein described particularly with reference to the examples.

33. (new) A process as claimed in claim 2, wherein acid catalyst in step (a) is sulphonic acid and its salts with organic bases or salt of inorganic acids with organic bases.

34. (new) A process as claimed in claim 2 , wherein said acid catalyst is selected form the group comprising of p-toluene sulfonic acid, methane sulfonic acid, pyridine hydrochloride, pyridine hydrobromide, pyridine methane sulfonate, pyridine p-toluene sulphonate, picoline hydrochloride, picoline hydrobromide, picoline methane sulfonate, picoline p-toluene sulphonate, lutidine hydro chloride, lutidine hydrobromide, lutidine methane sulfonate, lutidine p-toluene sulphonate.

35. (new) A process as claimed in claim 2, wherein said polar aprotic solvent in step (a) is selected from group comprising of amide functional group such as dimethylformamide (DMF), dimethylacetamide (DMAC), N-methylpyrrolidinone (NMP), N-methylacetamide, N-methylformamide, , N,N-dimethylpropionamide, sulphoxide functional group such as dimethylsulfoxide, sulfolane, and ethers such as tetrahydrofuran (THF) and dioxane.

36. (new) A process as claimed in claim 2, wherein step (a) is carried out in mixture of polar aprotic solvent with organic solvent, capable of removing water azeotropically such as toluene, cyclohexane and the like

37. (new) A process as claimed in 2, wherein said step (a) is carried out at 90°C to 140° C.

38. (new) A process as claimed in claim 2, wherein said step (a) is carried out for 10 to 20 hrs and more preferably for 12 to 18 hrs.

39. (new) A process as claimed in claim 2, wherein brominating agent in said step (c) is bromine.

40. (new) A process as claimed in claim 2, wherein Lewis acid used as catalyst in said step (c) is selected form aluminum chloride zinc chloride and stannous chloride.

41. (new) A process as claimed in claim 2, wherein organic solvent in said step (c) is selected from halogenated, nonhalogenated organic solvents.

42. (new) A process as claimed in claim 2, wherein base used in step (d) is selected from alkaline earth metal carbonate, bicarbonate, acetate.

43. (new) A process as claimed in claim 2, wherein organic solvent used in step (d) is selected from alcohols, halogenated solvents or mixtures thereof.

44. (new) A process as claimed in claim 2, wherein said step (d) can be carried out without isolating 2-bromo-4-(phthalimido)-cyclohexanone of formula (VI) prepared in said step (c).

45. (new) A process as claimed in 2, wherein said step (d) is carried out *in situ* with thiourea.

46. (new) A process as claimed in claim 2, wherein organic base used in said step (e) is triethyl amine, pyridine, dimethy aniline, lutidines, picolines and DBU, preferably triethyl amine.

47. (new) A process as claimed in claim 2, wherein said step (f) comprises the steps of

(i) treating *in situ* or racemic 2,6-diamino-4,5,6,7-tetrahydro benzothiazole of formula (VIII), obtained in step (d) with (L) –tartric acid to give (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole.

(ii) isolating pure (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole

(iii) converting pure (S) tartrate salts of 2,6-diamino-4,5,6,7-tetrahydro benzothiazole to (S)-2,6-diamino-4,5,6,7-tetrahydro benzothiazole of formula (II).